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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,562	12/05/2001	Daniel R. Salomon	20331-00002 (080060-0002)	2653
28534 7590 08/21/2007 MIRICK, O'CONNELL, DEMALLIE & LOUGEE, LLP 1700 WEST PARK DRIVE WESTBOROUGH, MA 01581			EXAMINER MOHAMED, ABDEL A	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 08/21/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/006,562	<b>Applicant(s)</b> SALOMON ET AL.	
	<b>Examiner</b> Abdel A. Mohamed	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13, 14, 16-18, 20, 22 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13, 14, 16-18, 20, 22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### **CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/12/07 has been entered.

#### **ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS**

2. The amendment and remarks filed 06/12/07 are acknowledged, entered and considered. In view of Applicant's request claims 1-12 have been canceled and claims 13, 14, 20 and 24 have been amended. Claims 13, 14, 16-18, 20, 22 and 24 are now pending in the application. The rejection under 35 U.S.C. 103(a) over the prior art of record is withdrawn in view of Applicant's amendment and remarks filed 06/12/07. However, if Applicant overcomes the new rejection set *infra* under 35 U.S.C. 112, first paragraph for new matter by amending the claims, the previous rejection under 35 U.S.C. 103(a) over the prior art of record would be reinstated.

#### **NEW GROUNDS OF REJECTIONS**

##### **CLAIMS REJECTION-35 U.S.C. 112, <sup>1st</sup> PARAGRAPH**

Art Unit: 1654

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13, 14, 16-18, 20, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Independent claim 13 and claims depending thereof as original filed contain new matter because the original specification does not appear to support for "the administration of cyclosporin A (CSA) and 2-chlorodeoxyadenosine (2-CDA) to the allograft recipient in a coordinated dosage regime comprising days on which both CSA and 2-CDA are administered and days on which only CSA is administered". The instant specification on page 10, lines 7-18 describe the therapeutically effective amount of 2-CDA and cyclosporin. On page 5, line 26 to page 6, line 22 states that Figure 1 shows the administration to rats of 5 mg CSA/Kg body mass/day for two weeks and 5 mg CSA/Kg 3 times/week until sacrificed at 90 days post transplant. Figure 3 demonstrates the administration of 5 mg CSA/Kg body mass/day for two weeks and 5 mg CSA/Kg 3 times /week thereafter, and 2 -CDA at 1 mg/Kg/week until sacrificed at 90 days post transplant. The instant specification on page 10, line 27 through Tables 1-5 pages 16 disclose treatment with various combinations of CSA and 2-CDA. On page

Art Unit: 1654

19, line 6 to page 22, line 23 the instant specification describes the treatment regime for CSA and 2-CDA at various dosages and dates (i.e., time periods). Thus, independent claim 13 and claims depending thereof have no support for the limitations for "the administration of cyclosporin A (CSA) and 2-chlorodeoxyadenosine (2-CDA) to the allograft recipient in a coordinated dosage regime comprising days on which both CSA and 2-CDA are administered and days on which only CSA is administered". Therefore, there is no disclosure as currently claimed because no alternative period was disclosed when both given (i.e., CSA in combination with 2-CDA) followed by only one (i.e., only CSA). Thus, Applicant respectfully requested to either cancel all unsupported subject matter or to show where such subject matter has support from the original disclosure.

#### **CLAIMS REJECTION-35 U.S.C. 112<sup>2nd</sup> PARAGRAPH**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 13, 14, 16-18, 20, 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite and confusing because the claim as drafted does not identify the dosage regime and/or dosage period on which CSA and 2-CDA and/or only CSA are administered, respectively. Also, there is no correlation between independent claim 13 and dependent claims 14, 18 and 20 with respect to time period. Appropriate clarification is required.

Art Unit: 1654

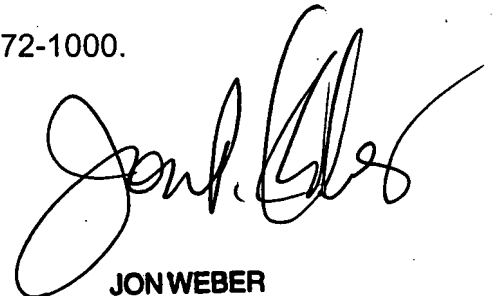
### CONCLUSION AND FUTURE CORRESPONDANCE

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**

*AM* Mohamed/AAM  
August 16, 2007